2009 Health Care Reform Principles

As organizations committed to ensuring access to high quality laboratory testing for all Americans, we join together in calling upon the nation’s policymakers to ensure that any effort to reform the nation’s health care system adequately addresses and incorporates the important role that laboratory medicine, and the professionals performing laboratory tests, play in the diagnosis, prognosis, and management of disease.

We believe that the increasing attention to – and emphasis on – the need to contemporaneously improve quality while reducing unnecessary costs, are critical to addressing the myriad challenges facing the nation’s health care system. Laboratory tests are extremely valuable tools for improving patient outcomes while reducing overall costs and serve as an essential basis for subsequent critical medical decision-making. As such, laboratory testing can play an essential role in supporting related health care reform goals of increasing investment in prevention and wellness and improving patient safety and outcomes.

The nation’s clinical laboratories and laboratory professionals wish to work collaboratively with others to meet the challenges and achieve the goals of national health reform efforts. To that end, as individual organizations and as the Clinical Laboratory Coalition, we stand ready to work with all policymakers to help shape and improve the future of health care in our nation.

Laboratory Tests and Professionals: Critical Components in Disease Diagnosis, Prognosis, and Treatment

Laboratory test results inform up to 70 percent of all medical decision making. As the first point of intervention, laboratory tests serve as the foundation for the diagnosis and management of conditions like cardiac disease, HIV, cancer, diabetes, kidney disease, and infectious diseases. For example:

- Laboratory tests play a key role in managing diabetes to ensure that (1) blood-sugar levels are being maintained in normal ranges and (2) costly and debilitating complications from the disease, like kidney failure, blindness, amputations, and stroke are prevented. Effective diabetes management improves quality of life for patients and helps reduce and prevent adverse events, which in turn, has the potential to save the health care system billions down the line. The same can be said for tests that monitor kidney disease, where effective management can slow down and even prevent further progression.

- Screening tests for cancer like the Pap test, which may be coupled with an HPV test, and Fecal Occult Blood Test (FOBT) detect disease even before symptoms are present, allowing the cancer to be treated at its earliest and most treatable stage. This saves lives, improves quality of life, and eliminates the increased cost of treating more advanced late-stage disease. Since cervical cancer screening began, the rate of death from the disease has dropped a remarkable 75 percent in the U.S.
Clinical Laboratory Coalition
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• No leukemia or other form of cancer is diagnosed or managed without laboratory tests. Cutting edge laboratory tests, particularly in the area of molecular diagnostics and genetics, promise to focus and personalize medicine in this area. Laboratory tests are already emerging that can determine if specific chemotherapeutic agents used to treat cancer will work for an individual. Tests that detect over-expression of the HER2/neu gene can determine increased risk of the recurrence of breast cancer and a worse prognosis, and predict if Herceptin, a drug used to treat breast cancer, would be effective. Tests of this kind allow more efficient and effective treatment of disease, and will avoid subjecting patients to treatments that are ineffective and may cause serious side effects.

• Laboratory tests play a significant role in the detection and tracking of infectious diseases. Tests not only identify infectious agents responsible for more serious forms of disease like oxacillin/methicillin-resistant *Staphylococcus aureus* (MRSA) infections, they also are used to identify carriers of these agents. The latter application may represent an effective means of lowering the rate of transmission in hospitals and other healthcare facilities, and could save healthcare dollars by more effective use of high dollar isolation procedures. Thus, laboratory detection of MRSA aids in triaging patients for early intervention facilitating decreased costs associated with healthcare-associated infections (HAIs).

Priorities and Concerns Regarding Ensuring Access to Timely Testing and Better Care

The Clinical Laboratory Coalition supports access to care for all Americans, and believes that expanded access to health care likely will improve care by providing timely access to clinical laboratory testing. To that end, the Clinical Laboratory Coalition calls upon Congress and the Administration to ensure that any expansion of access to health care supports patients’ access to clinical laboratory services and maintains laboratories’ ability to continue to provide quality services to patients. Specifically, the nation’s clinical laboratories are united in advocating that any national health reform effort:

• **Ensure patient access to laboratory services, including wellness and prevention services, and recognize that laboratory medicine contributes to improved health and a more efficient use of health care resources.** Laboratory testing is necessary for quality patient care. To help ensure patient care is efficient and effective, laboratory tests must be accurate, reliable, and reproducible and must be used to help prevent and detect adverse health conditions in their earliest and most treatable stages. Effective clinical laboratory testing will help to facilitate public health and safety, while minimizing/reducing overall health care spending.

• **Ensure improved health for patients by fostering innovations in clinical laboratory diagnostics that enhance quality of care.** Technology is playing a crucial role in the current health care debate. Health care providers and the broader health care professional community are developing new and better methods to assist the medical and laboratory communities in identifying and treating disease. This innovative ability is critical to improving patient care and must be facilitated through adequate reimbursement. Clinical laboratories play an essential role in providing quality health care and should be reimbursed at a level that fully recognizes the value of laboratory tests.
• Broaden the potential impact and availability of personalized medicine to improve patient care by providing continuing support for innovation and research in laboratory medicine. Increasingly, scientific advances in human genetics and biomarker research are moving our health care system towards personalized patient care, whereby health care professionals can select the most appropriate test for the individual, detect disease earlier, and determine the optimal therapy. Health care reform can assist this promising field by providing incentives for the co-development of drugs and laboratory tests, facilitating the adoption of electronic medical records and reimbursing for genetic testing services at a level that fully recognizes their value.

• Develop and promote health information technology infrastructure to reduce medical errors and improve patient care. Given the anticipated increased demand for laboratory testing stemming from expanded access to care, more data will be transmitted between laboratories and health care providers, usually through the use of information systems. Therefore, it is essential that electronic health record systems be integrated and interoperable to ensure the timely and accurate delivery of data to inform clinical decision-making. Seamless and effective communication between laboratories and other health care providers will serve patients better, help improve outcomes, and decrease costs by eliminating duplicate testing that often can occur during an outpatient-inpatient transition. Likewise, health information technology can and should be leveraged to provide the clinical decision support needed to assist clinicians in selecting appropriate tests and interventions that are supported by evidence-based clinical guidelines but are often underutilized, resulting in suboptimal health outcomes and avoidable downstream costs. It is therefore important that clinical laboratories are included as qualifying entities for current and future health information technology grants and other federal support. Equally important is assurance of interoperability of clinical laboratories and the data they provide with the public health system to ensure rapid recognition and control of infectious disease outbreaks as well as other shared community or other population-based threats.

• Ensure that there are sufficient, well-trained, and qualified health care personnel to serve patient needs. To address current and anticipated demand for laboratory services, a concerted effort must be undertaken to continue to recruit, educate, and train additional laboratory professionals. Given the current anticipated shortage of laboratory professionals, and the increasing age of the current workforce, it is essential to support federal efforts to develop an adequate, well-trained clinical laboratory workforce by fully funding the Title VII Health Professions Programs housed at the Health Resources and Services Administration.

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American Association for Clinical Chemistry
American Clinical Laboratory Association
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